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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/517,382	05/24/2005	Ulrik Darling Larsen	ALB.017	4711

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VOLENTINE & WHITT PLLC
ONE FREEDOM SQUARE
11951 FREEDOM DRIVE SUITE 1260
RESTON, VA 20190

EXAMINER	
SHABMAN, MARK A	
ART UNIT	PAPER NUMBER
2856	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/517,382	LARSEN ET AL.	
	Examiner	Art Unit	
	MARK SHABMAN	2856	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 September 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *22-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *22-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/26/2008, 11/19/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

Applicant's arguments filed on 25 September 2008 have been fully considered but they are not persuasive.

With regards to claim 22, Applicant argues that the limitation of "a diameter of the orifice is in a range from 10 μm to 1000 μm" would not have been an obvious variation of the Hanss or Kiesewetter reference due to the operating principles of the two apparatuses. It is argued that changing the size of the orifice would cause the apparatuses of both Hanss and Kiesewetter to function differently as the inventions are based on the operating principle that the orifice is smaller than the diameter of the particle (blood cell) passing through it. It is true that the size of the orifice in both Hanss and Kiesewetter was chosen to be smaller than the diameter of a typical red blood cell (between 5-9 μm) for this reason, however the courts have held that apparatus claims must be structurally distinguishable from the prior art in terms of structure, not function. See In re Danley, 120 USPQ 528, 531 (CCPA 1959); and Hewlett-Packard Co. 1l. Bausch and Lomb, Inc., 15 USPQ2d 1525, 1528 (Fed. Cir. 1990). The Courts have held that the manner of operating an apparatus does not differentiate an apparatus claim from the prior art, if the prior art apparatus teaches all of the structural limitations of the claim. See Ex Parte Masham, 2 USPQ2d 1647 (BPAI 1987). As claimed, the manner in which the claimed invention is to be used is not of significance as long as there exists reasoning for modifying the structure as is claimed.

The apparatus of Hanss operates under the same basic principles as that of the current application in that there exists two chambers 11, 12 which when under a constant current cause the particles of one chamber (i.e. the "mixing chamber") to pass through a membrane into the second chamber (i.e. the "collection chamber"). The reason that the apparatus of Hanss is capable of functioning as it does is due to the elasticity and deformability of the red corpuscle which is passing through the membrane. One of ordinary skill in the art at the time of invention would have realized such a characteristic and modified the membrane orifice size to accommodate transmission of any size particle which may be incapable of deforming as much.

It is also noted that the apparatus of Hanss is designed for study of the deformability of Human corpuscles. If however a researcher was to be working with cells of a larger diameter, such as those of many fish, it would have been desirable to enlarge the orifice diameter to allow for the blood cells to pass through and thus it would be reasonable to increase the size of the orifice to 10 μm or larger.

In addition, Applicant describes on page 7 lines 16-17 of the specification an instance in which the diameter of the orifice is between 5 and 200 μm showing that the size of the orifice is based on the particle size which is to be passing through. One of ordinary skill in the art at the time of invention would realize the operating principles of Hanss apparatus would allow for the structure to be used in the desired manner with no modification, as long as the diameter of the particles under test is less than that of the orifice which is entirely possible as described on page 7 line 9 of the current application. One of ordinary skill in the art would realize that apparatus of Hanss is capable of

testing the transmission of particles smaller than the diameter of the orifice from one chamber to another with no modification necessary.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 31 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding **claim 31**, it is unclear how the deviation of the orifice diameter is determined. "A longitudinal axis" could be any number of axes depending on where they are drawn. In such a case, the percentages claimed would correspond to different values for each axis, causing the actual values to be indefinite.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 22-29 and 31-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hanss US Patent 4,835,457 (hereinafter referred to as Hanss) in view of Graham US Patent 6,111,398 (hereinafter referred to as Graham).

Regarding **claim 22 and 23**, Hanss discloses an apparatus for the measurement of red blood cell deformity comprising two separate chambers 2a, 2b forming a housing, each comprising a cavity 11, 12. Cavity 11 (collection chamber) is separated by cavity 12 (mixing chamber) by a membrane 5 made of plastic material or polymer (column 2 line 37). The membrane contains an "orifice" in the pores which allow particles to pass through from one cavity to the other (column 2 line 38).

The description of the device further describes the electrodes 13, 14 as comprising a constant current through them as seen in figure 3. A change in voltage in the sensor characterizes the movement of the cells through the membrane. By spacing the electrodes apart in such a manner and keeping the current through them constant, the resulting electric field at the center of the orifice would be "homogenous" as claimed.

The interior of the conduit of Graham is described as being hydrodynamically smooth and further describes a diameter of conduits used to be within a range of 10μm to 2000μm, or 30μm to 200μm for other applications (column 3 line 15). It would have been obvious to one of ordinary skill in the art at the time of invention to use the same sized orifices of Graham with the membrane of Hanss depending on the size of the particles passing through or if the cells under test were larger than those normally found in a human.

Regarding **claim 24**, Graham discloses the radius of the curvature of the rounded edges to be 1/2 the diameter of the orifice. As the Graham reference teaches towards rounding the orifice opening by a radius equal to one half of the diameter, it would have been obvious to one of ordinary skill in the art at the time of invention to change that amount to ¼ the diameter if desired to also improve the flow properties.

Regarding **claim 25**, the interior of the conduit of Graham is described as being hydrodynamically smooth and further describes a diameter of conduits used to be as low as 0.010mm (10μm). At a size of 10μm, in order for a particle or blood cell to pass through, roughness on the internal surface of the orifice could at a maximum be 5 μm before complete blockage could occur due to rough spots contacting one another which is within the range of 0-5μm claimed.

Regarding **claim 26**, the interior of the conduit of Graham is described as being hydrodynamically smooth and further describes a diameter of conduits used to be within a range of 10μm to 2000μm, or 30μm to 200μm for other applications (column 3 line 15). Since the apparatus of Graham works on similar principles as that of Hanss by applying a current source both sides of a membrane to induce transmission of a particulate across the membrane, it would have been obvious to one of ordinary skill in the art at the time of invention to use the same sized orifices of Graham with the membrane of Hanss to allow for different sized particles to pass through.

Regarding **claim 27**, the interior of the conduit of Graham is described as being hydrodynamically smooth and further describes a diameter of conduits used to be within a range of 10μm to 2000μm, or 30μm to 200μm for other applications (column 3 line

15). It would have been obvious to one of ordinary skill in the art at the time of invention to use the same sized orifices of Graham with the membrane of Hanss as these values are known in the art to be acceptable for the intended use of the invention.

Regarding **claim 28**, Graham notes in column 3 line 23 that a conduit wherein the length is equal to 3/4 of the diameter is acceptable and favorable for use. If the diameter is between 10μm to 2000μm as described in line 15 of the same column, then the length would fall in the range claimed.

Regarding **claim 29**, the apparatus of Hanss could be intended for "single use" if so desired by the user. It would have been obvious to one of ordinary skill in the art at the time of invention to create a sampling device in which the parts which were to come in contact with a blood sample were disposable to help prevent the spread of any infectious diseases contained therein to the outside of the chambers.

Regarding **claim 31**, while there is no explicit indication of the "deviation of the orifice diameter along a longitudinal axis of the orifice" ranging from +/-1% to +/-10%, it would have been obvious to one of ordinary skill in the art at the time of invention to have manufactured the orifices as close to ideal as possible which be with as little deviation as possible, i.e. less than 10%.

Regarding **claim 32**, the interior of the conduit of Graham is described as being hydrodynamically smooth and further describes a diameter of conduits used to be within a range of 10μm to 2000μm, (column 3 line 15). It would have been obvious to one of ordinary skill in the art at the time of invention to use the same sized orifices of Graham

with the membrane of Hanss as these values are known in the art to be acceptable for the intended use of the invention and fall within the 10-50 µm range claimed.

Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hanss in view of Graham as applied to claim 22 above in further view of Berndtsson International Publicaiton WO 99101742 (hereinafter referred to as Berndtsson).

Regarding **claim 30**, Hanss in view of Graham discloses the claimed invention with the exception of the bore in the outer surface of the housing and the sampling member. Berndtsson discloses a disposable sampling device for particle counting apparatus comprising a housing with a bore in the outer surface 55 (figure 2, page 5 line 29) allowing for liquid entrance into the housing, and a sampling member 52 positioned in the housing. The sampling member comprises a cavity 53 for receiving and holding a liquid sample (figures 3 and 4) and is "movably positioned as claimed. In the first postion as seen in figures 2-4, the cavity is "in communication with the bore for entrance of the liquid" as claimed. In the second position as illustrated in figures 5-8, the cavity is in communication with a "mixing chamber" 61 allowing for the fluid to be discharged as seen in figure 6. It would have been obvious to one of ordinary skill in the art at the time of invention to combine the teachings of Berndtsson with those of Hanss and Graham to allow for a blood sample to enter the system directly from a donor such as the one seen in figures 3 and 4, denoted by the reference character F. This allows for faster, on site testing without the need for external syringes or pumps.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARK SHABMAN whose telephone number is (571)270-3263. The examiner can normally be reached on M-F 8:00am - 4:30pm, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Hezron Williams can be reached on (571) 272-2208. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/M. S./
Examiner, Art Unit 2856
/Hezron Williams/
Supervisory Patent Examiner, Art Unit 2856